

FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ 180.00

Complete if Known

Application Number 09/435,992
Filing Date November 8, 1999
First Named Inventor NABIL HANNA
Examiner Name Phillip Gambel
Art Unit 1644
Attorney Docket No. 037003-0275478

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

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033975

PILLSBURY WINTHROP LLP

The Director is authorized to: (check all that apply)

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FEE CALCULATION

1. BASIC FILING FEE

Large Entity Small Entity

Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) (\$ 0.00

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims - 20** = X =
Independent Claims - 3** = X =
Multiple Dependent =

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description
1202	2202	9 Claims in excess of 20
1201	2201	43 Independent claims in excess of 3
1203	2203	145 Multiple dependent claim, if not paid
1204	2204	43 ** Reissue independent claims over original patent
1205	2205	9 ** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$ 0.00

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Small Entity

Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for <i>ex parte</i> reexamination	
1804	920	1804	920	Requesting publication of SIR prior to Examiner action	
1805	1,840	1805	1,840	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	180.00
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$ 180.00

SUBMITTED BY

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Signature

Date

April 29, 2004

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Docket Number: 037003-0275478

PATENT APPLICATION

Client Reference: 1999-30-0466A



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re the Application of

HANNA et al.

Group Art Unit: 1644

Application No.: 09/435,992

Examiner: Phillip Gambel

Filed: November 8, 1999

Confirmation No.: 5990

For: TREATMENT OF B CELL MALIGNANCIES USING ANTI-CD40L ANTIBODIES IN COMBINATION WITH ANTI-CD20 ANTIBODIES AND/OR CHEMOTHERAPEUTICS AND RADIOTHERAPY

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 CFR 1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449. One copy of each reference is submitted herewith. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first official action on the merits, but before the mailing date of a final rejection or notice of allowance. Payment of the requisite fee under 37 CFR 1.17(p) is enclosed.

04/30/2004 WABRHAM1 00000074 033975 09435992
01 FC:1806 180.00 DA

Respectfully submitted,

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APR 29 2004

Atty. Dkt. No.
037003-0275478Client Ref.
1999-30-0466A

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Applicant: NABIL HANNA et al.

Appln. No.: 09/435,992

Filing Date: November 8, 1999

Date: April 29, 2004

Page 1 of 4

Examiner: Phillip Gambel

Group Art Unit: 1644

U.S. PATENT DOCUMENTS

Examiner's Initials*		Document Number	Date MM/YYYY	Name (Family Name of First Inventor)	Class	Sub Class	Filing Date (if appropriate)
	AR	5,443,953	08/1995	Hansen			
	BR	5,484,892	01/1996	Tedder			
	CR	5,500,362	03/1996	Robinson			
	DR	5,595,721	01/1997	Kaminski			
	ER	5,674,492	10/1997	Armitage			
	FR	5,677,165	10/1997	de Boer			
	GR	5,677,180	10/1997	Robinson			
	HR	5,681,722	10/1997	Newman			
	IR	5,686,072	11/1997	Uhr			
	JR	5,750,105	05/1998	Newman			
	KR	5,736,137	04/1998	Anderson			
	LR	5,776,456	07/1998	Anderson			
	MR	5,789,554	08/1998	Morita			
	NR	5,801,227	09/1998	Fanslow			
	OR	5,821,337	10/1998	Carter			
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	QR	5,874,082	02/1999	de Boer			
	RR	5,874,085	02/1999	Mond			
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	UR	5,945,513	08/1999	Aruffo			
	VR	6,011,138	01/2000	Reff			
	WR	6,113,898	09/2000	Anderson			

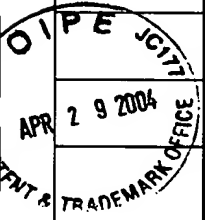
FOREIGN PATENT DOCUMENTS

		Document Number	Date MM/YYYY	Country	Inventor Name		English Abstract	Translation Readily Available
	XR	WO 95/06666	03/1995	PCT	Noelle			
	YR	WO 96/12741	05/1996	PCT	Bonnefoy			
	ZR	WO 98/41641	09/1998	PCT	Fitzgerald			
	AAR	WO 98/42378	10/1998	PCT	Goldenberg			
	BBR	WO 98/56418	12/1998	PCT	Lam			
	CCR	WO 00/20864	04/2000	PCT	Barbera-Guillem			
	DDR	555 880 A2	08/1993	EP	Aruffo			

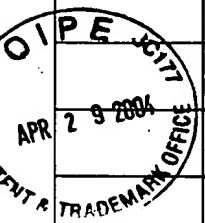
OTHER (Including in this order Author, Title, Periodical Name, Date, Pertinent Pages, etc.)

EER	Abaza MS et al., "Effects of amino acid substitutions outside an antigenic site on protein binding to monoclonal antibodies of predetermined specificity obtained by peptide immunization: demonstration with region 94-100 (antigenic site 3) of myoglobin," <i>J Protein Chem</i> , 1992, 11: 433-444.
FFR	Anderson D et al., "A primatized MAb to human CD4 causes receptor modulation, without marked reduction in CD4+ T cells in chimpanzees: in vitro and in vivo characterization of a MAb (IDEC-CE9.1) to human CD4," <i>Clin Immunol Immunopathol</i> , 1997, 84: 73-84.

	GGR	Berinstein NL et al., "Association of serum Rituximab (IDEC-C2B8) concentration and anti-tumor response in the treatment of recurrent low-grade or follicular non-Hodgkin's lymphoma," <i>Ann Oncol</i> , 1998, 9: 995-1001.
	HHR	Bohlen H et al., "Cytolysis of leukemic B-cells by T-cells activated via two bispecific antibodies," <i>Cancer Res</i> , 1993, 53: 4310-4314.
	IIR	Brams P et al., "A humanized anti-human CD154 monoclonal antibody blocks CD154-CD40 mediated human B cell activation," <i>Int Immunopharmacol</i> , 2001, 1: 277-294.
	JJR	Byrd JC et al., "The mechanism of tumor cell clearance by rituximab in vivo in patients with B-cell chronic lymphocytic leukemia: evidence of caspase activation and apoptosis induction," <i>Blood</i> , 2002, 99: 1038-1043 (abstract only).
	KKR	Campana D et al., "Human B cell development. I. Phenotypic differences of B lymphocytes in the bone marrow and peripheral lymphoid tissue," <i>J Immunol</i> , 1985, 134: 1524-1530.
	LLR	Carbone A et al., "CD40 ligand is constitutively expressed in a subset of T cell lymphomas and on the microenvironmental reactive T cells of follicular lymphomas and Hodgkin's disease," <i>Am J Pathol</i> , 1995, 147: 912-22.
	MMR	Carbone A et al., "Expression of functional CD40 antigen on Reed-Sternberg cells and Hodgkin's disease cell lines," <i>Blood</i> , 1995, 85:780-789.
	NNR	Clodi K et al., "Unbalanced expression of Fas and CD40 in mantle cell lymphoma," <i>Br J Haematol</i> , 1998, 103: 217-219.
	OOR	Clynes R et al., "Fc receptors are required in passive and active immunity to melanoma," <i>Proc Natl Acad Sci USA</i> , 1998, 95: 652-656.
	PPR	Coiffier B et al., "Rituximab (anti-CD20 monoclonal antibody) for the treatment of patients with relapsing or refractory aggressive lymphoma: a multicenter phase II study," <i>Blood</i> , 1998, 92: 1927-1932.
	QQR	Czuczman MS et al., "Treatment of patients with low-grade B-cell lymphoma with the combination of chimeric anti-CD20 monoclonal antibody and CHOP chemotherapy," <i>J Clin Oncol</i> , 1999, 17: 268-276.
	RRR	Demidem A et al., "Chimeric anti-CD20 (IDEC-C2B8) monoclonal antibody sensitizes a B cell lymphoma cell line to cell killing by cytotoxic drugs," <i>Cancer Biother Radiopharm</i> , 1997, 12: 177-186.
	SSR	Endo K, "[Current status of nuclear medicine in Japan]," <i>Gan To Kagaku Ryoho</i> , 1999, 26: 744-748.
	TTR	Engel P et al., "Identification of the ligand-binding domains of CD22, a member of the immunoglobulin superfamily that uniquely binds a sialic acid-dependent ligand," <i>J Exp Med</i> , 1995, 181: 1581-1586.
	UUR	Flores-Romo L et al., "Inhibition of an in vivo antigen-specific IgE response by antibodies to CD23," <i>Science</i> , 1993, 241:1038-1046.
	VVR	Fournier S et al., "CD23 antigen regulation and signaling in chronic lymphocytic leukemia," 1992, <i>J Clin Invest</i> , 89:1312-1321.
	WWR	Funakoshi S et al., "Inhibition of human B-cell lymphoma growth by CD40 stimulation," <i>Blood</i> , 1994, 83: 2787-2794.
	XXR	Griggs ND et al., "The relative contribution of the CD28 and gp39 costimulatory pathways in the clonal expansion and pathogenic acquisition of self-reactive T cells," <i>J Exp Med</i> , 1996, 183(3):801-810.
	YYR	Grossbard ML et al., "Monoclonal antibody-based therapies of leukemia and lymphoma," <i>Blood</i> , 1992, 80: 863-878.
	ZZR	Gruss HJ et al., "CD40/CD40 ligand interactions in normal, reactive and malignant lymphohematopoietic tissues," <i>Leuk Lymphoma</i> , 1997, 24: 393-422.
	AAAR	Johnson PW et al., "Isolated follicular lymphoma cells are resistant to apoptosis and can be grown in vitro in the CD40/stromal cell system," <i>Blood</i> , 1993, 82: 1848-1857.
	BBBR	Kano Y et al., "In vitro cytotoxic effects of fludarabine (2-F-ara-A) in combination with commonly used antileukemic agents by isobologram analysis," 2000, <i>Leukemia</i> , 14(3):379-88.
	CCCR	Kiesel S et al., "Removal of cells from a malignant B-cell line from bone marrow with immunomagnetic beads and with complement and immunoglobulin switch variant mediated cytotoxicity," <i>Leuk Res</i> , 1987, 11: 1119-1125.
	DDDR	Konstantinov SM et al., "Cytotoxic efficacy of bendamustine in human leukemia and breast cancer cell lines," 2002, <i>J Cancer Res Clin Oncol</i> , 128(5):271-278.
	EEER	Ledbetter JA et al., "Agonistic and antagonistic properties of CD40 mAb G28-5 are dependent on binding valency," <i>Circ Shock</i> , 1994, 44: 67-72.
	FFFR	Leget GA et al., "Use of rituximab, the new FDA-approved antibody," <i>Curr Opin Oncol</i> , 1998, 10: 548-551.



GGGR	Linderoth et al., "Immunohistochemical expression of CD23 and CD40 may identify prognostically favorable subgroups of diffuse large B-cell lymphoma: a Nordic Lymphoma Group Study," 2003, <i>Clin Cancer Res</i> , 9(2):722-728.
HHHR	Lopez-Matas M et al., "Quantitative expression of CD23 and its ligand CD21 in chronic lymphocytic leukemia," 2000, <i>Hematologica</i> , 85:1140-1145.
IIIR	Maloney DG et al., "IDEC-C2B8 (Rituximab) anti-CD20 monoclonal antibody therapy in patients with relapsed low-grade non-Hodgkin's lymphoma," <i>Blood</i> , 1997, 90: 2188-2195.
JJJR	Maloney DG et al., "Newer treatments for non-Hodgkin's lymphoma: monoclonal antibodies," <i>Oncology (Huntingt)</i> , 1998, 12: 63-76.
KKKR	Matutes E et al., "Morphological and immunophenotypic features of chronic lymphocytic leukemia," 2000, <i>Rev Clin Exp Hematol</i> 4:22-47.
LLLR	McLaughlin P et al., "Rituximab chimeric anti-CD20 monoclonal antibody therapy for relapsed indolent lymphoma: half of patients respond to a four-dose treatment program," <i>J Clin Oncol</i> , 1998, 16: 2825-2833.
MMMR	McLaughlin P et al., "Clinical status and optimal use of rituximab for B-cell lymphomas," <i>Oncology (Huntingt)</i> , 1998, 12: 1763-9; discussion 1769-70, 1775-1777.
NNNR	Metkar SS et al., "CD40-ligation-mediated protection from apoptosis of a Fas-sensitive Hodgkin's-disease-derived cell line," <i>Cancer Immunol Immunother</i> , 1998, 47:104-112.
OOOR	Molica S et al., "Cellular expression and serum circulating levels of CD23 in B-cell chronic lymphocytic leukemia. Implications for prognosis," 1996, <i>Hematologica</i> , 81:428-433.
PPPR	Montserrat E et al., "Treatment of B-cell chronic lymphocytic leukaemia: current status and future perspectives," <i>J Intern Med Suppl</i> , 1997, 740: 63-67.
QQQR	Murphy WJ et al., "Antibodies to CD40 prevent Epstein-Barr virus-mediated human B-cell lymphomagenesis in severe combined immune deficient mice given human peripheral blood lymphocytes," <i>Blood</i> , 1995, 86: 1946-1953.
RRRR	Nakamura T et al., "In vitro IgE inhibition in B cells by anti-CD23 monoclonal antibodies is functionally dependent on the immunoglobulin Fc domain," <i>Int J Immunopharmacol</i> , 2000, 22: 131-141.
SSSR	Nguyen DT et al., "IDEC-C2B8 anti-CD20 (rituximab) immunotherapy in patients with low-grade non-Hodgkin's lymphoma and lymphoproliferative disorders: evaluation of response on 48 patients," <i>Eur J Haematol</i> , 1999, 62: 76-82.
TTTR	Nishida S et al., "Apoptosis-inducing effect of a new bisphosphonate, YM529, on various hematopoietic tumor cell lines," 2003, <i>Biol Pharm Bull</i> , 26(1):96-100.
UUUR	Nitschke L et al., "CD22 is a negative regulator of B-cell receptor signalling," <i>Curr Biol</i> , 1997, 7: 133-143.
VVVR	Ohnishi K et al., "[New antitumor drugs for non-Hodgkin's lymphoma]," <i>Gan To Kagaku Ryoho</i> , 1998, 25: 2223-2228.
WWWR	Pedersen IM et al., "The chimeric anti-CD20 antibody rituximab induces apoptosis in B-cell chronic lymphocytic leukemia cells through a p38 mitogen activated protein-kinase-dependent mechanism," <i>Blood</i> , 2002, 99: 1314-1319 (abstract only).
XXXR	Piro LD et al., "Extended Rituximab (anti-CD20 monoclonal antibody) therapy for relapsed or refractory low-grade or follicular non-Hodgkin's lymphoma," <i>Ann Oncol</i> , 1999, 10: 655-661.
YYR	Plumas J et al., "Tumor B cells from non-Hodgkin's lymphoma are resistant to CD95 (Fas/Apo-1)-mediated apoptosis," <i>Blood</i> , 1998, 91: 2875-2885.
ZZR	Pene J et al., "IgE production by normal human lymphocytes is induced by interleukin 4 and suppressed by interferons gamma and alpha and prostaglandin E2," <i>Proc Natl Acad Sci USA</i> , 1988, 85: 6880-6884.
AAAAR	Pozzato G et al., "Effects of alpha-interferon and steroids on CD23 expression and release in B-cell chronic lymphocytic leukemia," <i>Haematologica</i> , 1994, 79: 205-212.
BBBBR	Press OW et al., "Treatment of refractory non-Hodgkin's lymphoma with radiolabeled MB-1 (anti-CD37) antibody," 1989, 7(8):1027-1038
CCCCR	Press OW et al., "Monoclonal antibody 1F5 (anti-CD20) serotherapy of human B cell lymphomas," <i>Blood</i> , 1987, 69: 584-591.
DDDDR	Ravetch JV et al., "Fc receptors," <i>Annu Rev Immunol</i> , 1991, 9: 457-492.
EEEEER	Rector E et al., "Detection and characterization of monoclonal antibodies specific to IgE receptors on human lymphocytes by flow cytometry," <i>Immunology</i> , 1985, 55: 481-488.
FFFFR	Reff ME et al., "Depletion of B cells in vivo by a chimeric mouse human monoclonal antibody to CD20," <i>Blood</i> , 1994, 83: 435-45.



	GGGGR	Remstein ED et al., "Despite apparent morphologic and immunophenotypic heterogeneity, Waldenstrom's macroglobulinemia is consistently composed of cells along a morphologic continuum of small lymphocytes, plasmacytoid lymphocytes, and plasma cells," 2003, <i>Semin Oncol</i> , 30(2):182-186.
	HHHHR	Renard N et al., "Demonstration of functional CD40 in B-lineage acute lymphoblastic leukemia cells in response to T-cell CD40 ligand," <i>Blood</i> , 1996, 87: 5162-5170.
	IIIIIR	San Miguel JF et al., "Immunophenotypic analysis of Waldenstrom's macroglobulinemia," 2003, <i>Semin Oncol</i> , 30(2):187-195.
	JJJJR	Sarfati M et al., "Elevation of IgE-binding factors in serum of patients with B cell-derived chronic lymphocytic leukemia," <i>Blood</i> , 1988, 71: 94-98.
	KKKKR	Sherr E et al., "Binding the low affinity Fc epsilon R on B cells suppresses ongoing human IgE synthesis," <i>J Immunol</i> , 1989, 142: 481-489.
	LLLLR	Stamenkovic I, et al., "The B-cell antigen CD22 mediates monocyte and erythrocyte adhesion," <i>Nature</i> , 1990, 345: 74-77.
	MMMMR	Stamenkovic I et al., "The B lymphocyte adhesion molecule CD22 interacts with leukocyte common antigen CD45RO on T cells and alpha 2-6 sialyltransferase, CD75, on B cells," <i>Cell</i> , 1991, 66: 1133-1144.
	NNNNR	Tallman MS, "Monoclonal antibody therapies in leukemias," <i>Semin Hematol</i> , 2002, 39: 12-19 (abstract only).
	OOOOR	Valle A et al., "Activation of human B lymphocytes through CD40 and interleukin 4," <i>Eur J Immunol</i> , 1989, 19: 1463-1467.
	PPPPR	Wang Z et al., "Induction of bcl-x by CD40 engagement rescues slg-induced apoptosis in murine B cells," <i>J Immunol</i> , 1995, 155: 3722-3725.
	QQQQR	White LJ et al., "Inhibition of apoptosis in a human pre-B-cell line by CD23 is mediated via a novel receptor," <i>Blood</i> , 1997, 90: 234-243.
	RRRRR	Wohlschlaeger CH et al., "Aberrant immunophenotypes of mantle cell lymphomas," 2003 <i>Leuk Lymphoma</i> , 44(2):269-273.
	SSSSR	Worm M et al., "CD40 ligation induces lymphotoxin alpha gene expression in human B cells," <i>Int Immunol</i> , 1994, 6: 1883-1890.
	TTTTTR	Younes A et al., "Elevated levels of biologically active soluble CD40 ligand in the serum of patients with chronic lymphocytic leukaemia," <i>Br J Haematol</i> , 1998, 100: 135-141 (abstract only).
	UUUUR	Zhu et al., "Investigatory and analytical approaches to differential gene expression profiling in mantle cell lymphoma," 2002, <i>Br J Haematol</i> , 119(4):905-915.

Examiner

Date Considered:

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.